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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,209	03/29/2004	Gunter A. Hofmann	GTI 1360-3	5135

7590 05/02/2007

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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/813,209	HOFMANN ET AL.	
	Examiner	Art Unit	
	Christopher D. Koharski	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *114-132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *114-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 2/22/2007 in which the current pending claim set was verified and the application was revived for continued prosecution. Currently claims 114-132 are pending for examination in this application.

Information Disclosure Statement

Examiner acknowledges that no information disclosure statement (IDS) was filed with this application, accordingly, the examiner is not considering any information disclosure statements filed at this time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 114-116, 119-126,128 and 132 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobsen et al. (5,860,975). Jacobsen et al. discloses a multipathway controlled drug delivery source.

Regarding claims 114-116, 119-126,128 and 132, Jacobsen et al. discloses a series of multiple devices (400) capable of electroporation comprising a needle free injector configured to act a first electrode (370) position to be in contact with a patients skin capable of inducing at least one liquid jet through a nozzle (350), a second electroporation electrode array comprising ring electrodes (410) and an electrical connection to a current source configured for creating an electric potential (Figure 6) (col 10, ln 40-70, col 11, ln 1-40). Additionally, Jacobsen et al. discloses various sensors for patient and control module (10) programming (col 4, ln 55-60, col 4, ln 45-60, col 5, ln 1-65) and the use of an ionized solvent for movement of the drug through a created electric field col 10, ln 40-70, col 11, ln 1-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 117-118 and 127 are rejected under 35 U.S.C 103(a) as being unpatentable over Jacobsen et al. in view of Zhang et al. (6,266,560). Jacobsen et al. meets the claim limitations as described above except for the specific micropatch and meander electrode.

However, Zhang et al. teaches an electrically assisted transdermal delivery system.

Regarding claims 117-118 and 127, Zhang et al. teaches an electroporation system that uses varied different electrodes that comprise a meander or micropatch electrode (col 8, ln 50-60, col 9, ln 1-40).

At the time of the invention, it would have been obvious to use the electrodes of Zhang et al. in order to incorporate different electrodes for different electrical characteristics and therapeutic absorption rates. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Zhang et al. (col 8, ln 50-60, col 9, ln 1-40).

Claim Rejections - 35 USC § 103

Claims 129-131 are rejected under 35 U.S.C 103(a) as being unpatentable over Jacobsen et al. in view of Hofmann (5,273,525). Jacobsen et al. meets the claim limitations as described above except for the specific electrical source parameters.

However, Hofmann teaches an injection and electroporation apparatus for drug delivery.

Regarding claims 129-131, Hofmann teaches a delivery device (10) that uses an electrical pulse generator (16) to induce electroporation through needles (12) with the pulse being bi-polar and consisting of a square wave (col 3, ln 10-40).

At the time of the invention, it would have been obvious to use the electrical source generator of Hofmann with the system of Jacobsen et al. because the addition of varied electrical waveforms allows for varied delivery modalities for various drug and drug targets. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hofmann (col 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 4/25/07

CDK

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